

REMARKS

Status of the Claims

The present Office Action addresses and rejects claims 1-21 and 23-35, however claims 13, 14, 19, 20, 24, and 32 are withdrawn. Applicant respectfully requests reconsideration in view of the remarks herein.

Amendments to the Claims

Independent claim 1 is amended to include subject matter from cancelled claim 6 and from amended claim 7, and in particular to recite that the closure mechanism has a tapered bore extending therethrough that axially aligns with the bore in the spinal anchoring element when the closure mechanism is mated to the spinal anchoring element, and to recite a set screw having a head that is received within the tapered bore in the closure mechanism, and a threaded shaft adapted to threadably engage threads in the bore in the spinal anchoring element to mate the closure mechanism to the spinal anchoring element. Claims 5, 7, and 13 are amended to reflect the amendment to claim 1.

Independent claim 21 is amended to include subject matter from cancelled claim 26, and in particular to recite that the locking mechanism is adapted to sit within a tapered bore extending through the closure mechanism, and to recite that the locking mechanism is adapted to threadably mate with a bore formed in the spinal anchoring element to mate the closure mechanism to the spinal anchoring element. Claims 24 and 26 are cancelled, and claims 27 and 28 are amended to reflect the amendment to claim 21.

Support for these amendments can be found throughout the specification and drawings, for example in Figure 1 and in paragraph [0041]. No new matter is added.

Rejections Pursuant to 35 U.S.C. § 102

Claims 1-9, 12, 15, 18, 21, 23, and 25-31 are rejected pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Patent Publication No. 2005/0171537 of Mazel et al. (“Mazel”). Applicant respectfully disagrees.

In relevant part, claim 1 recites a set screw having a head that is received within a tapered bore formed. Independent claim 21 recites, in relevant part, a locking mechanism adapted to sit within a tapered bore extending through the closure mechanism.

Mazel does not disclose the claimed invention for at least two reasons. First, Mazel fails to teach a closure mechanism having a tapered bore. As shown in Figure 1 of Mazel, which is reproduced at right, the upper element (7) does not have a tapered bore. Rather, the bore is cylindrical and has no tapered portion therein. Second, Mazel fails to teach or suggest a set screw having a head that is received within any tapered bore. The threaded plug (28) of Mazel does not have a head at all. The only portion of Mazel that could be considered to be a head on a set screw would be the clamping nut (14) which threadably mates to the plug (28). The clamping nut (14), however, sits on the proximal surface of the upper element (7), and thus is not received within any bore, much less a tapered bore.

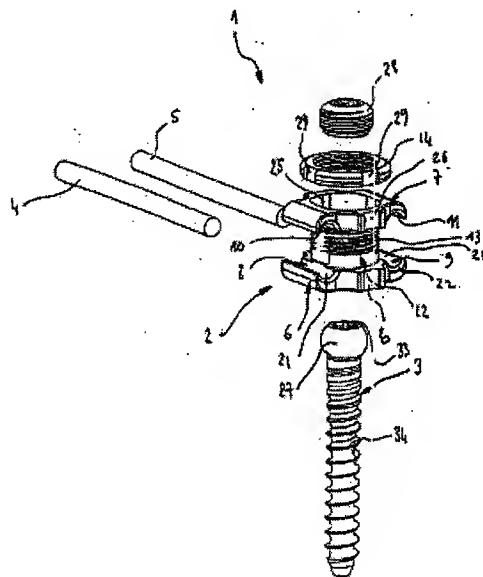


Figure 1

Accordingly, claims 1 and 21, as well as claims 2-5, 7-9, 12, 15, 18, 23, 25, and 27-31 which variously depend therefrom, distinguish over Mazel and represent allowable subject matter.

Rejections Pursuant to 35 U.S.C. § 103

Independent Claims 1 and 21

Claims 1-9, 12, 15, 18, 21, 23, and 25-31 are rejected pursuant to 35 U.S.C. §103(a) as being made obvious by U.S. Patent No. 7,008,423 of Assaker et al. ("Assaker")¹. Claims 1-6, 8-12, 15, 18, 21, 23, 25, 26, 28-31, and 33 are rejected pursuant to 35 U.S.C. §103(a) as being made obvious

¹ The Office Action on pages 5 and 7 identifies Assaker as U.S. Patent No. 7,008,426. Applicant assumes that this is a typographical error and that the Examiner intended the rejection to be over U.S. Patent No. 7,008,423. Applicant respectfully requests clarification and a non-final office action, should a subsequent office action be issued rejecting any claims over U.S. Patent No. 7,008,426, if the Examiner intended otherwise.

by U.S. Patent No. 5,620,443 of Gertzbein et al. ("Gertzbein"). Applicant respectfully disagrees.

Assaker

The Examiner admits that Assaker fails to disclose a closure mechanism being removably mated to the spinal anchoring element and therefore asserts that it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device with a closure mechanism being removably mated to the spinal anchoring element because constructing a formerly integral structure in various elements only involves routine skill in the art.

Even if Assaker was modified as suggested by the Examiner, the claimed invention would still not result for at least two reasons. First, as shown in Figure 9 of Assaker, reproduced at right, the clamping screw (10), which the Examiner likens to a locking mechanism or a set screw, clearly does not sit have a head that sits within any tapered bore formed in the top half of the connector (6), which the Examiner likens to a closure mechanism. The opposite is true in Assaker with the head (44) clearly sitting *on* and *extending proximally beyond* the proximal surface of the connector (6).

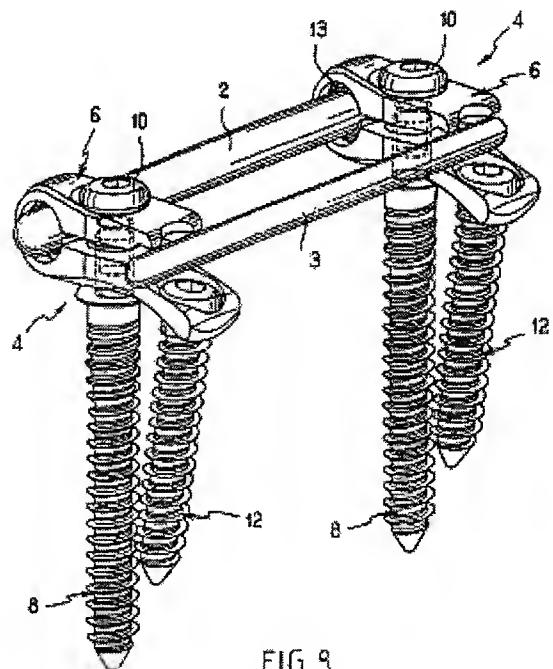


FIG. 9

Second, the screw (10) does not threadably engage threads in the bore of the bottom half of the connector (6), which the Examiner likens to a spinal anchoring element. The bore in the bottom half of the connector (6) is not threaded. The screw (10) thus cannot threadably engage the bore in the bottom half of the connector (6) as required by claim 1. Moreover, the shaft (42) of the screw (10) is inserted into and contained within a bore in the main screw (8) to lock the screw (8) to the connector (6). The shaft (42) thus cannot threadably engage the bore in the bottom half of the connector (6) because not only does it never contact that bore, the main screw (8) extends entirely therethrough.

Accordingly, claims 1 and 21, as well as claims 2-5, 7-9, 12, 15, 18, 23, 25, and 27-31 which variously depend therefrom, distinguish over Assaker and represent allowable subject matter.

Gertzbein

The Examiner admits that Gertzbein fails to disclose a closure mechanism being removably mated to the spinal anchoring element and therefore asserts that it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device with a closure mechanism being removably mated to the spinal anchoring element because constructing a formerly integral structure in various elements only involves routine skill in the art.

Even if Gertzbein was modified as suggested by the Examiner, the claimed invention would still not result for at least three reasons. First, the Examiner admits on page 11 of the Office Action that the fastener (40) of Gertzbein is not a set screw.

Second, as shown in Figures 1 and 3 of Gertzbein, reproduced below, the fastener (40), which the Examiner likens to a locking mechanism, clearly does not sit within a tapered bore formed in the top half of the connector (15), which the Examiner likens to a closure mechanism. The opposite is true in Gertzbein with the entire fastener (40) clearly sitting *on* the proximal surface of the connector (15).

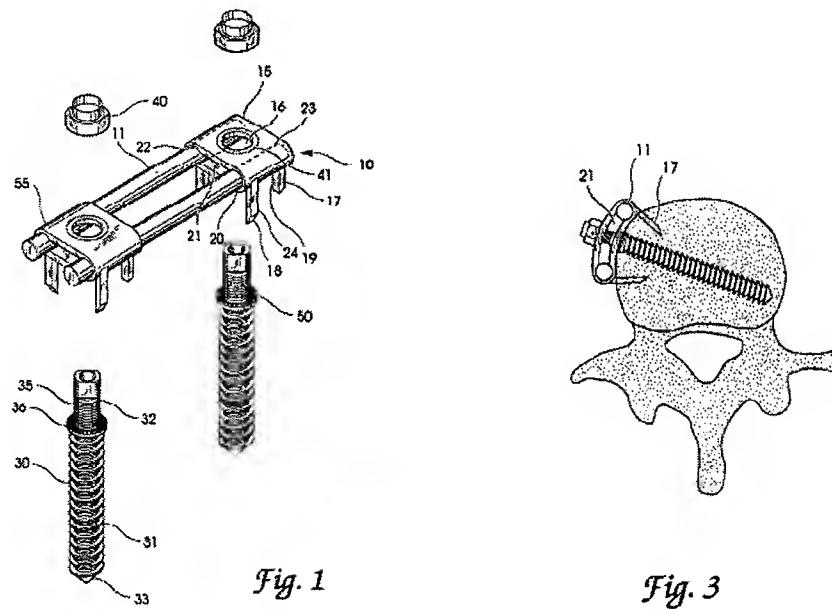


Fig. 1

Fig. 3

Third, the fastener (40) does not threadably engage threads in the bore of the bottom half of the connector (15), which the Examiner likens to a spinal anchoring element. Being a nut and not a screw, the fastener (40) cannot threadably engage the bore in the bottom half of the connector (15). Moreover, the fastener (40) cannot engage the bore in the bottom half of the connector (15) at all. Not only does the fastener (40) sit atop the connector (15), the proximal post (32) of the bolt (31) extends through the bore of the bottom half of connector (15), thereby preventing the fastener (40), or any other fastener, from threadably engaging that bore.

Accordingly, claims 1 and 21, as well as claims 2-5, 8-12, 15, 18, 23, 25, 28-31, and 33 which variously depend therefrom, distinguish over Gertzbein and represent allowable subject matter.

Shih

The Examiner does not reject either independent claim as anticipated by or obvious over U.S. Patent No. 6,136,002 of Shih et al. (“Shih”), but the Examiner provides Shih as an evidentiary reference. Specifically, the Examiner states that Shih shows that clamps meant for holding rods can be constructed as two separate pieces, closure mechanism (14) and spinal anchoring element (12). As discussed above, even if either of Assaker and Gertzbein were modified to have their respective connectors separated into two pieces as suggested by the Examiner, the claimed invention would not result.

Applicant notes that while Shih does disclose that the locking nut (S) extends through a bore in the cover plate (14) and threads into a hole (H) in the vertebral plate (12), the locking nut (S) does not engage any bore that any of the bolts (B) extend through. The locking nut (S) can only engage the bores in both the cover plate (14) and the vertebral plate (12) because those bores do not engage either of the bolts (B). Rather, the bolts (B) are offset from the locking nut (S) and are held into place with the rods (40).

Dependent Claims 10, 11, and 33

Claims 10, 11, and 33 are rejected pursuant to 35 U.S.C. §103(a) as being made obvious by Mazel in view of Shih and by Assaker in view of Shih. At least for the reasons explained above,

Mazel does not anticipate and Assaker does not make obvious either of independent claims 1 and 21 from which claims 10, 11, and 33 variously depend. Shih is only relied on for dependent claim features, namely for bone engaging members (spikes) extending distally from the inferior surface of each of the first and second end portions. Shih does not remedy the deficiencies of Mazel or Assaker. Accordingly, claims 10, 11, and 33 are allowable at least because they depend from an allowable base claim.

Dependent Claims 16, 17, 34, and 35

Claims 16, 17, 34, and 35 are rejected pursuant to 35 U.S.C. §103(a) as being made obvious by Mazel in view of U.S. Patent Publication No. 2004/0236327 of Paul et al. (“Paul”), by Assaker in view of Paul, and by Gertzbein in view of Paul. At least for the reasons explained above, Mazel does not anticipate and neither Assaker nor Gertzbein makes obvious either of independent claims 1 and 21 from which claims 16, 17, 34, and 35 variously depend. Paul is only relied on for dependent claim features, namely that a spinal fixation element can be flexible and can be formed from a bioabsorbable material, and does not remedy the deficiencies of Mazel, Assaker, or Gertzbein. Accordingly, claims 16, 17, 34, and 35 are allowable at least because they depend from an allowable base claim.

Dependent Claims 7 and 27

Claims 7 and 27 are rejected pursuant to 35 U.S.C. §103(a) as being made obvious by Gertzbein in view of Assaker. At least for the reasons explained above, Gertzbein does not make obvious independent claims 1 and 21 from which claims 7 and 27 respectively depend. Assaker is only relied on for dependent claim features, namely the locking mechanism being a set screw, and does not remedy the deficiencies of Gertzbein. Accordingly, claims 7 and 27 are allowable at least because they depend from an allowable base claim.

Conclusion

Accordingly, all claims are now in condition for allowance, and allowance thereof is respectfully requested. Applicant’s amendment of the claims does not constitute a concession that the claims are not allowable in their unamended form. The Examiner is encouraged to telephone the

undersigned attorney for Applicant if such communication is deemed to expedite prosecution of this application.

No extension of time is believed to be due with this filing. In the event that a petition for an extension of time is required to be submitted at this time, Applicant hereby petitions under 37 C.F.R. 1.136(a) for an extension of time for as many months as are required to ensure that the above-identified application does not become abandoned.

All fees due are believed to be paid. The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 141449, under Order No. 101896-251.

Dated: June 3, 2009

Respectfully submitted,

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